

Remarks

**I. Status Of The Claims**

Claims 1-27 are active in this application.

**II. Support For The Amendment**

Claims 4, 6, 20 and 24-26 have been amended in order to remove improper multiple dependencies.

No new matter has been added by this amendment.

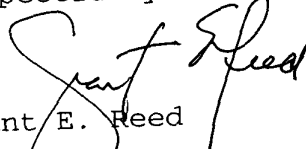
**III. Unity Of Invention Practice, Not Restriction Practice, Applies To The Present Application**

Applicants respectfully point out that the present application is the U.S. national phase of international application no. PCT/US00/15026. U.S. restriction practice under MPEP section 803 is not applicable to the U.S. national phase of an international application. See MPEP section 1893.03(d). Instead, unity of invention practice applies to an international application. *Id.*

Applicants respectfully request that the U.S. Examiner apply unity of invention practice, not restriction practice, to the claims of the present application. It is believed that unity of invention exists between the claims of the present application.

If the Examiner believes that personal communication would expedite the prosecution of the present application, the Examiner is encouraged to contact the undersigned at the number provided below.

Respectfully submitted,

  
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**Version Of Amended Claims With Markings To Show Changes Made**

4. (Once Amended) Crystals according to claim 1 [any one of Claims 1-3], wherein the volume mean spherical equivalent diameter is from 1.5 microns to 4.5 microns.

6. (Once Amended) A process for preparing crystals according to claim 1 [any one of Claims 1-5], comprising;

a) preparing a crystallization solution comprising insulin, an insulin analog, a derivatized insulin or a derivatized insulin analog, a buffer, a salt and a divalent cation;

b) combining the crystallization solution of step a) with a nucleating seed suspension; and

c) allowing time for the seeded crystallization solution of step b) to generate the crystals [according to any one of Claims 1 - 5].

20. (Once Amended) A pharmaceutical composition for administration by inhalation by mouth comprising the crystals according to claim 1 [of any one of Claims 1 - 5].

24. (Once Amended) Use of the crystals according to claim 1 [of any one of Claims 1 - 5] to prepare a medicament for the treatment of diabetes or hyperglycemia by mouth.

25. (Once Amended) A method of using the crystals according to claim 1 [any one of the Claims 1 - 5] to treat diabetes or hyperglycemia using a device to administer the crystals by inhalation via the mouth to a patient in need of such treatment.

26. (Once Amended) A method of treating diabetes comprising administering the pharmaceutical composition according to claim 20 [any one of the Claims 20 - 23] to a patient in need thereof to regulate blood glucose levels in the patient.